

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vermox 100mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg mebendazole.

Excipients: Each tablet also contains Sunset Yellow (E110).

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.

Product imported from Greece.

Faintly orange circular, flat, half-scored, bevel-edged tablet with 'Me 100' inscribed on one side and 'JANSSEN' on the other.

The half-score is only to facilitate breaking for ease of swallowing and not to divide into equal halves.

4 CLINICAL PARTICULARS

As per PA0330/046/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0330/046/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Sodium Starch Glycollate
Talc
Maize Starch
Saccharin Sodium
Magnesium Stearate
Hydrogenated Vegetable Oil
Tetarome Orange
Colloidal Dioxide Silica
Sodium Laurilsulfate
Sunset Yellow (E110)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strip and outer package of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

Keep the blister in the outer carton in order to protect from light.

6.5 Nature and contents of container

Outer carton containing a blister strip
Pack size 6

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Ltd.
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/145/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th February 2011

10 DATE OF REVISION OF THE TEXT

April 2017